



# **CLINICAL RELEVANCE**

Among men with nonmetastatic castration-resistant prostate cancer already receiving androgen-deprivation therapy (the standard of care for this condition), the metastasis-free survival and time to symptomatic progression were significantly longer with apalutamide than with placebo.



# **SERVICE DELIVERY ENABLERS**

Prostate cancer diagnosis in LMICs is hindered by limited access to diagnostic tools and healthcare resources.

Prostate Specific Antigen (PSA) testing, imaging, and biopsies are scarce, leading to late-stage diagnosis.

Access to cost-effective second-line androgen-targeted therapies like abiraterone and enzalutamide is also inadequate in many LMICs.



# **DISEASE BURDEN**

Prostate cancer is the second most common cancer in men and the fourth most common cancer overall (7.3% of all new cancer cases in 2020). Prostate cancer incidence rates are rising in many populations in Sub-Saharan Africa where men are approximately twice as likely to be diagnosed with prostate cancer before the age of 45 as Caucasian men.



# INTELLECTUAL PROPERTY LANDSCAPE

Apalutamide primary patents are expected to expire in 2027. Secondary patents may provide exclusivity until 2033-2038 in many LMICs.





Janssen

# REGULATORY

Product approved by stringent regulatory authorities.
Potential sublicensees of apalutamide could rely on mechanisms like USFDA Paragraph III, Swissmedic MAGHP or EU-M4all for quality assurance.
Bioequivalence studies are necessary. Biowaivers will not be an option.



### **MANUFACTURING**

Solid dispersion technique is used for manufacture of tablets. No challenges with respect to excipients or final packaging. Since it is an androgenic receptor inhibitor, special facility might be required. Shelf life is 3 years at room temperature.

#### **MARKET**

The product's growth is evidenced by presence in >75 countries including a few LMICs, generic versions are available. However, there seems to be limited access in the public sector.



